



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/826,522 | 04/16/2004 | Geert Plaetnick | D0590.70011US02 | 2890 |
| 23628 7590 12/07/2009 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206 | | | | |
| EXAMINER | | | | |
| SHIN, DANA H | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1635 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 12/07/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/826,522

Applicant(s)

PLAETINCK ET AL.

Examiner

DANA SHIN

Art Unit

1635

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-41, 70-74 and 80-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-41, 70-74 and 80-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date 10-23-2009
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 23, 2009 has been entered.

Status of Claims

Claims 30-41, 70-74, and 80-83 are pending and under examination on the merits in the instant case.

Response to Arguments

Applicant's arguments and the declaration filed under 37 CFR 1.132 submitted with the RCE are acknowledged, and have been entered. The arguments and Declaration have been fully considered but are moot in view of the new grounds of rejections. That is, the arguments and Declaration are directed to rejections that are based on references that are not relied on in the new rejections, thus the arguments and Declaration are not persuasive to overcome the instant rejections. See below.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on October 23, 2009 is being considered by the examiner, except citation C32, which is in non-English language.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 365(c) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application Nos. GB9814536.0 and GB982715.2, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The foreign priority documents merely provide *E. coli* lacking RNase III and containing a vector comprising two opposing T7 promoters. It is found that neither of the foreign priority documents provides adequate support and written description for the instantly claimed T3 and SP6 promoters (see claim 34) in the manner provided by the first paragraph of 35 U.S.C. 112. Hence, the benefit of the foreign priority date is denied for claim 34 and therefore the filing date of 09/347,311 (July 2,

1999) will be the earliest effective filing date for claim 34. If applicant believes that the subject matter claimed in claim 34 is adequately disclosed and supported by either of the foreign documents, applicant is advised to point out the particulars in response to this Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 30-36, 39, 74, 80, and 83 are rejected under 35 U.S.C. 102(e) as being anticipated by Graham (US 6,573,099 B2).

Graham discloses a cell comprising an isolated genetic construct “which is capable of delaying, repressing or otherwise reducing the expression of a target gene in an animal cell which is transfected with said genetic construct, wherein said genetic construct comprises at least two copies of a structural gene sequence and each copy of said structural gene sequence is separately placed under the control of a promoter which is operable in said cell, and wherein said structural gene sequence comprises a nucleotide sequence which is substantially identical to at least a region of said target gene, wherein at least one copy of said structural gene sequence is placed operably in the sense orientation under the control of an individual promoter sequence, and wherein at least one other copy of said structural gene sequence is placed operably in the antisense orientation under the control of another individual promoter sequence.” See claim 4. Graham teaches that one can also introduce the isolated genetic construct into a plant cell or a

yeast cell or a bacterial cell and transform the cell by utilizing promoters suitable for plant, yeast, and bacterial cells, for example, plant, yeast, and bacteria-derived promoters such as bacteriophage T7 promoter, bacteriophage T3 promoter, and SP6 promoter. See column 8, lines 4-25. Graham teaches that one can use two identical promoters or preferably use two different promoter sequences. See column 12, lines 42-50. Since the “isolated genetic construct” of Graham meets the structural requirements set forth for the “expression vector” claimed in the instant case, the yeast cell or bacterial cell comprising the isolated genetic construct of Graham would necessarily and inherently contain a double-stranded RNA produced by the isolated genetic construct that repress and reduces the target gene expression in the cell, absent evidence to the contrary. Note that when a rejection is based on a reference teaching a product appearing to be substantially identical to the claimed product, and when the examiner presents reasoning tending to show inherency, the burden shift to the applicant to show an unobvious difference. See MPEP 2112: “[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency’ under 35 U.S.C. 102, on prima facie obviousness’ under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted].”

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 30-41, 70-74, and 80-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Timmons et al. (*East Coast Worm Meeting Abstract 180*, May 12, 1998, applicant's citation - note that applicant has incorrectly indicated that the publication date for this abstract is June 27, 2002 in the IDS submitted on April 16, 2004) in view of McAllister et al. (US 5,017,488), Conkling et al. (US 5,459,252, citation of record), and Talkad et al. (*Journal of Bacteriology*, 1978, 135:528-541, citation of record).

Timmons et al. disclose bacteria comprising a single promoter-containing "myo3:unc22 dsRNA" expression vector, wherein unc22 is obtained from the *C. elegans* genome and myo3 is a muscle tissue-specific promoter. Timmons et al. do not teach bacteria or yeast or plant comprising a construct containing two promoters that flank the DNA sequence producing a dsRNA.

McAllister et al. teach that one can use a dual promoter cassette construct comprising two different RNA polymerase promoter sequences located at each end of the desired DNA sequence, thereby forming a DNA plasmid vector construct comprising the desired DNA sequence flanked by two different RNA polymerase promoters selected from a T3 RNA polymerase promoter, a bacteriophage T7 RNA polymerase promoter, and SP6 RNA polymerase

promoter. For example, they teach that the dual promoter cassette construct produces a synthetic RNA oligomer "oriented such that the direction of transcription from the T3 promoter is counter clockwise" whereas the transcription of a synthetic RNA oligomer "from the SP6 promoter is oriented-clockwise". See column 2, lines 62-66. They teach that the dual promoter system is highly efficient in transcribing the RNA product of the DNA sequence and can be used in various genetic and experimental applications. Most importantly, they disclose that their invention also includes "the transformed microorganisms like bacteria which contain the vectors of the invention, and the progeny of such microorganisms." See column 3, lines 47-49. See the entire reference including claims 1-3, 7-8, 13.

Conkling et al. teach that a root-specific promoter RB7 in an expression vector allows root-specific transcription and expression of an exogenous nucleotide sequence in a plant cell. See columns 5-8 and claims 1-13.

Talkad et al. teach *E. coli* strains that are deficient in RNase III. They teach that RNase III cleaves bacteriophage T7 RNAs as well as double-stranded RNAs. See the entire reference.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the expression vector construct of Timmons et al. by incorporating the teachings of McAllister et al. and Conkling et al., thereby obtaining cells of *C. elegans* or yeast or RNase III-deficient *E. coli* comprising an expression vector comprising two promoters oriented in opposite directions.

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success because the dual promoter system was known to be highly efficient in transcribing the RNA product of the DNA sequence and thus was suggested to be useful for making "the transformed microorganisms like bacteria which contain the vectors of the

invention, and the progeny of such microorganisms." as taught by McAllister et al. Further, since the use of root-specific promoters for expressing a gene of interest in the root of a plant was already known in the art as taught by Conkling et al., one of ordinary skill in the art wishing to produce a double-stranded RNA in the root of a plant would have been motivated to use two root-specific RB7 promoters in opposing directions (clock-wise and counter-clockwise) flanking the DNA sequence of interest. Further, since RNase III in bacteria was known to cleave and degrade bacteriophage T7 RNAs and double-stranded RNAs, it would have been apparent to a person of ordinary skill in the art to transform RNase III-deficient *E. coli* bacteria with the dual promoter system in order to allow the system to efficiently produce the double-stranded RNA product that remains preserved in the cells of *E. coli* bacteria. Since all skills, knowledge, and methodologies to arrive at the claimed invention were known in the art at the time the invention was made, the claimed invention taken as a whole would have been *prima facie* obvious at the time of filing.

Claims 30-41, 70-74, and 80-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fire et al. (WO 99/32619, citation of record) in view of Graham (US 6,573,099 B2), Ely et al. (US 5,837,848), and Talkad et al. (*Journal of Bacteriology*, 1978, 135:528-541, citation of record).

Fire et al. teach that one can inhibit target gene expression in a cell with an expression vector that synthesizes and produces two separate complementary strands and form an RNA duplex inside the cell, wherein the cell is a plant cell, a yeast cell, or a nematode cell such as *C. elegans* cell. They teach that bacteriophage RNA polymerase promoters such as T3, T7, and SP6 promoters are useful for transcribing and synthesizing RNA. Note that the provisional

application 60/068,562 filed on December 23, 1997 adequately supports the aforementioned teachings of Fire et al. See for examples claims 1, 14, 16, and 20 and pages 11 and 13. Fire et al. at the time of the priority filing date did not explicitly teach an expression vector comprising two opposing promoters, each of which transcribes and synthesizes each strand of a double-stranded RNA.

Graham discloses a cell comprising an isolated genetic construct “which is capable of delaying, repressing or otherwise reducing the expression of a target gene in an animal cell which is transfected with said genetic construct, wherein said genetic construct comprises at least two copies of a structural gene sequence and each copy of said structural gene sequence is separately placed under the control of a promoter which is operable in said cell, and wherein said structural gene sequence comprises a nucleotide sequence which is substantially identical to at least a region of said target gene, wherein at least one copy of said structural gene sequence is placed operably in the sense orientation under the control of an individual promoter sequence, and wherein at least one other copy of said structural gene sequence is placed operably in the antisense orientation under the control of another individual promoter sequence.” (emphasis added). See claim 4. Graham teaches that one can also introduce the isolated genetic construct into a plant cell or a yeast cell or a bacterial cell and transform the cell by utilizing promoters suitable for plant, yeast, and bacterial cells, for example, plant, yeast, and bacteria-derived promoters such as bacteriophage T7 promoter, bacteriophage T3 promoter, and SP6 promoter. See column 8, lines 4-25. Graham teaches that one can use two identical promoters or preferably use two different promoter sequences. See column 12, lines 42-50.

Ely et al. teach that one can use root-specific promoters to express a gene of interest in the roots of plants. They teach that the root-specific promoters are especially useful for

expressing an insecticidal toxin to aid the plant roots to resist insect attack. See the entire reference.

Talkad et al. teach *E. coli* strains that are deficient in RNase III. They teach that RNase III cleaves bacteriophage T7 RNAs as well as double-stranded RNAs. See the entire reference.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the two-promoter construction methodology of Graham to produce a double-stranded RNA in *C. elegans*, yeast, or RNase III-deficient *E. coli*.

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success because use of a promoter-containing expression vector to transcribe and produce a double-stranded RNA was already known in the art as taught by Fire et al., and because using an expression vector containing a single promoter and using an expression vector containing two opposing promoters were alternative methodologies or approaches to produce and express two separate copies of a gene of interest as taught by Graham. See and compare claims 3 and 4 of Graham. As such, an expression vector comprising a single promoter and an expression vector comprising two opposing promoters were art-recognized functional equivalents at the time the invention was made. Note that substituting art-recognized equivalents known for the same purpose is a well-established rationale in support of an obviousness rejection. See MPEP 2144.06. Further, since the industrial utility of a root-specific promoter-containing expression vector such that it can be used to express an insecticidal toxin to the root of a plant for protection of the root from insect attack was known in the art as taught by Ely et al., one of ordinary skill in the art wishing to produce a double-stranded RNA against an insecticidal toxin gene in a microorganism that can be applied to the root of a plant for protection against insect attack would have been motivated to make an expression vector comprising two

opposing root-specific promoters and transform the selected microorganism with the expression vector. Further, since RNase III in bacteria was known to cleave and degrade bacteriophage T7 RNAs and double-stranded RNAs, it would have been apparent to a person of ordinary skill in the art to transform RNase III-deficient *E. coli* bacteria with the dual promoter system in order to allow the system to efficiently produce the double-stranded RNA product that remains preserved in the cells of *E. coli* bacteria. Since all skills, knowledge, and methodologies to arrive at the claimed invention were known in the art at the time the invention was made, the claimed invention taken as a whole would have been *prima facie* obvious at the time of filing.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30-40, 70-74, 80-83 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-11 of copending Application No. 11/522,307. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the reference claims are drawn to a cell (*E. coli* bacterial cell or a yeast cell or a nematode cell) comprising a double-stranded RNA. Although the reference claims do not explicitly recite that the double-stranded RNA is produced from a vector comprising two promoters, the specification of the copending application teaches that one can use such vector for producing double-stranded RNA in a cell, wherein the promoters are selected from T3, T7, SP6 and root-specific promoters, wherein the sequence is obtained from the genome of an insect or *C. elegans*. See pages 8, 17, 20, 36. As such, the scope of the instant claims and that of the reference claims overlap with each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 30-40, 70-74, 80-83 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-25 of copending Application No. 11/666,017. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the reference claims are drawn to a cell (*E. coli* bacterial cell or a yeast cell or a nematode cell) comprising a double-stranded RNA. Although the reference claims do not explicitly recite that the double-stranded RNA is produced from a vector comprising two promoters, the specification of the copending application teaches that one can use such vector for producing double-stranded RNA in a cell, wherein the promoters are selected from T7, SP6 and root-specific promoters. See pages 39-44. As such, the scope of the instant claims and that of the reference claims overlap with each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 30-40, 70-74, 80-83 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-28, 34-35 of copending Application No. 11/666,021. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the reference claims are drawn to a cell (*E. coli* bacterial cell or a yeast cell) comprising a double-stranded RNA. Although the reference claims do not explicitly recite that the double-stranded RNA is produced from a vector comprising two promoters, the specification of the copending application teaches that one can use such vector for producing double-stranded RNA in a cell, wherein the promoters are selected from T7, SP6 and root-specific promoters. See pages 1, 18-19, 30-32. As such, the scope of the instant claims and that of the reference claims overlap with each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 30-41, 70-74, 80, 83 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34-39 of copending Application No. 12/055,607. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the reference claims are drawn to a bacterial cell of *E. coli* comprising a DNA construct producing a double-stranded RNA, wherein the construct comprises two promoters. Although the reference claims do not explicitly recite that T3, T7, SP6, wherein the bacterial cell is RNase III-deficient strain, the specification of the copending application teaches the limitations. See pages 5-6, 23. The specification also teaches that one can express dsRNA obtained from *C. elegans*. See pages 21-22. As such, the scope of the instant claims and that of the reference claims overlap with each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 30-41, 70-74, 80, 83 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-10, 12 of copending Application No. 12/087,537. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the reference claims are drawn to a cell (bacterial cell or a yeast cell) comprising a double-stranded RNA. Although the reference claims do not explicitly recite that the double-stranded RNA is produced from a vector

comprising two promoters, the specification of the copending application teaches that one can use such vector for producing double-stranded RNA in a cell, wherein the promoters are selected from T3, T7, SP6, wherein the bacterial cell is RNase III-deficient strain. See pages 30-31, 48. The specification also teaches that one can express dsRNA obtained from *C. elegans*. See page 17. As such, the scope of the instant claims and that of the reference claims overlap with each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 30-41, 70-74, 80, 83 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-27 of U.S. Patent No. 7,358,069 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the reference claims are drawn to a bacterial cell of *E. coli* comprising a DNA construct producing a double-stranded RNA, wherein the construct comprises two promoters. Although the reference claims do not explicitly recite that T3, T7, SP6, wherein the bacterial cell is RNase III-deficient strain, the specification of the U.S. Patent teaches the limitations. See columns 3 and 10. The specification also teaches that one can express dsRNA obtained from *C. elegans*. See column 10. As such, the scope of the instant claims and that of the reference claims overlap with each other.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, 7am-3:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tracy Vivlemore (Acting SPE) can be reached on 571-272-2914. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

/J. E. ANGELL/
Primary Examiner, Art Unit 1635